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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,881

12/07/2005

Koetsu Saito

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03/18/2008

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT

PAPER NUMBER

3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,881	Applicant(s) SAITO, KOETSU	
	Examiner HELENE BOR	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 1-6, 8 & 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buon (US Patent No. 4,494,548) and further in view of Nunomura et al. (US Patent No. 7,001,355 B2).

Claim 1 & 10: Buon teaches an ultrasonic probe (Figure 2, Element 2) comprising: an ultrasonic transducing part for transmitting and receiving an ultrasonic wave (Figure 2, Element 11); an outer case for storing the ultrasonic transducing part and an window (Figure 2, Element 20 & 38) and an acoustic medium [fluid] charged in the outer case (Col. 2, Line 52-57). Buon teaches the acoustic medium having the acoustic impedance and velocity matching that of human tissue, not 1,2-butylene glycol or 1,3-butylene glycol. However, Nunomura teaches wherein the acoustic medium contains butylene

Art Unit: 3768

glycol (Col. 11, Line 13-40) and specifically 1,3-butylene glycol. It would have been obvious to one of ordinary skill in the art to combine the teachings of Buon and Nunomura in order to use a composition that can effectively deliver the ultrasound to the skin (Col. 2, Line 10-18). Nunomura does not specifically mention 1,2-butylene glycol. However according to the Miller (Miller, L.M. "Investigation of selected potential environmental contaminants: ethylene glycols, propylene glycols and butylenes glycols: Final Report". Franklin Research Center, Philadelphia, PA. 01 May 1979. PB-80-109119), butylene glycol has four isomers, 1,3-, 1,4- 2,3- and 1,2-butylene glycol. It would have been obvious for one of ordinary skill in the art to substitute one of the four butylenes glycol known isomers for another in order to achieve the predictable result of a medium suitable for ultrasonic transmission.

Claim 2: Buon teaches the ultrasonic probe (Figure 2, Element 2) but fails to teach 1,3-butylene glycol. However, Nunomura teaches wherein the acoustic medium is formed of only butylene glycol (Col. 11, Line 13-40).

Claim 3: Buon teaches the ultrasonic probe (Figure 2, Element 2) but fails to teach the temperature range and butylene glycol. However, Nunomura teaches wherein the acoustic medium further contains at least one material that is soluble in 1,3 butylene glycol and a liquid with a temperature of no greater than 40° C (Col. 11, Line 13-40 & Col. 24, Line 41-42).

Claim 4: Buon teaches the ultrasonic probe (Figure 2, Element 2) but fails to teach 1,3-butylene glycol. However, Nunomura teaches wherein the material is at least one selected from the group consisting of ethylene glycol, 1,3-butylene glycol, and water

(Col. 11, Line 13-40).

Claim 5: Buon teaches the ultrasonic probe (Figure 2, Element 2) but fails to specifically teach 1,3-butylene glycol. However, Nunomura teaches wherein the material is 1,3-butylene glycol (Col. 11, Line 30-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Buon and Nunomura in order to use a composition that can effectively deliver the ultrasound to the skin (Col. 2, Line 10-18).

Claim 6: Buon teaches the ultrasonic probe (Figure 2, Element 2) but fails to teach specific wt % of butylene glycol. However, Nunomura teaches wherein the acoustic medium contains 25 to 100 wt % of butylene glycol (Col. 11, Line 13-15 & 30-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Buon and Nunomura in order to use a composition that can effectively deliver the ultrasound to the skin (Col. 2, Line 10-18).

Claim 8: Buon teaches the ultrasonic probe, comprising a mechanism for oscillating or rotating the ultrasonic transducing part (Figure 2, Element 23).

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buon (US Patent No. 4,494,548) and in view of Nunomura et al. (US Patent No. 7,001,355 B2) as applied above to 1-6 & 8-10 and further in view of Atala et al. (US Patent Application No. 2002/0055702 A1)

Claim 9: Buon and Numomura fail to teach the use of an array element. However, Atala teaches an ultrasonic probe, wherein the ultrasonic transducing part includes an array element in which a plurality of transducers are arranged (Page 5, Para 0036) to increase the magnitude of the ultrasound wave (Page 6, Para 0064). It would have

been obvious to one of ordinary skill in the art to modify the system of Buon and Numomura to include the multiple transducer arrangement as taught by Atala for increasing the magnitude of the ultrasound wave (Page 6, Para 0064).

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buon (US Patent No. 4,494,548) and in view of Nunomura et al. (US Patent No. 7,001,355 B2) as applied above to 1-6 & 8-10 and further in view of Ludwig (Ludwig, George. *The Velocity of Sound through Tissues and the Acoustic Impedance of Tissues*. The Journal of the Acoustical Society of America, Nov 1950: (22)(6) 862-866; enclosed herein) and in view of Schafer (Schafer, Mark E et al. *Use of Time Delay Spectrometry in Fluid Attenuation Measurement* Ultrasonics Symposium, 1989: 973-976; enclosed herein).

Claim 7: Buon teaches the ultrasonic probe, wherein the acoustic medium has an acoustic impedance of human tissue at a temperature of 20° C [room temperature inherent] (Col. 2, Line 52-57), and produces an ultrasonic at a frequency of 3 MHz (Col. 2, Line 25-29). Buon does not teach the range of acoustic impedance but puts forth a single value. However, Ludwig defines the acoustic impedance of human tissue as 1.58-1.70 Mrayl [converted value] and that 1.63 Mrayl is the average value of human tissue (Page 865, Table I). One of ordinary skill in the art at the time of the invention would have understood the definition of human tissue impedance and would have understood that fluids having an acoustic impedance within the defined range as taught by Ludwig would have been useable within the system of Buon. Buon fails to teach the acoustic medium having an attenuation of 0.07 to 0.091 dB/mm. However, Schafer

Art Unit: 3768

provides the acoustic attenuation properties for 1,3 Butylene Glycol (Page 976, Figure 3) for providing information to manufactures to chose the ideal fluid (Page 973, Part I).

It would have been obvious for one of ordinary skill in the art to understand the attenuation properties of fluids as taught by Schafer and to modify the system of Buon and Nunomura et al. to include the desired fluid as taught by Schafer in order to chose the ideal fluid (Page 973, Part I).

Response to Arguments

6. Applicant's amendment, see Page 5, filed 12/18/2007, with respect to the Title have been fully considered and are persuasive. The objection of the Title has been withdrawn.

7. Applicant's arguments, see 5, filed 12/18/2007, with respect to the rejection(s) of claim(s) 1-9 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Buon (US Patent No. 4,494,548) and further in view of Nunomura et al. (US Patent No. 7,001,355 B2). The Examiner agreed that the Applicant was correct with regards to the combination of Hakimuddin (US Patent No. 6,612,156 B1) and Numomura (US Patent No. 7,001,355 B2) in terms of structure. The Applicant presented the argument that 1, 2 butylene glycol produced unexpected and superior results and would not have been obvious to try. However, the Examiner disagrees that it would not be obvious to try 1,2 butylene glycol in place of 1,3 butylene glycol. The Examiner consulted the prior art of the time of the invention to understand the known relationship of the time between the isomers of butylene glycol and what

motivation existed for 1, 2 butylene glycol to be obvious to try. The Examiner further notes that butylene glycol has equivalent names in known art such as butanediols and dihydroxybutanes¹. Buon [cited above] teaches that the acoustic medium [fluid] must have an acoustic impedance and velocity matching that of human tissue (Col. 2, Line 52-57). Luwig [cited above] further defines the range of impedance of human tissue (Page 866, Table II). Examiner contends that one of ordinary skill in the art would consider the properties of a medium to match the human tissue. Schafer explains how acoustic impedance is well tabulated. In fact, using the known in the art Acoustic Impedance Equation, ρ (density) \times V (acoustic velocity) = Z (acoustic impedance), one can calculate the acoustic impedance by knowing the properties of a medium. Hawrylak'76 [cited below] provides a table of the density and velocity properties of 1, 2 butylene glycol and 1, 3 butylene glycol. Using the Acoustic Impedance Equation, one of ordinary skill would find that the Mrayl of 1, 2 butylene glycol is less than 1, 3 butylene glycol and within the range of acoustic impedance of human tissue as required by Buon. Schafer explains that while acoustic impedance information is easy to come by, acoustic attenuation are not readily available (Page 973, Part I) but points out more viscous fluids generally showed higher levels of attenuation as previous published work also showed (Page 975, Part V). Hawrylak'27 [cited below] teaches that 1, 3 butylene glycol has a greater viscosity than 1, 2 butylene glycol. Thus based on relationship of viscosity to attenuation as taught by Schafer and the viscosity properties of the butylene glycol isomers as taught by Hawrylak'27, one of ordinary skill in the art at the time of the

¹ "Chemical: Butylene Glycol". The Comparative Toxiogenomics Database. Mount Desert Island Biological Laboratory. < <http://ctd.mdibl.org/detail.go?type=chem&acc=D002072>>. 06 March 2008.

Art Unit: 3768

invention would expect 1, 2 butylene glycol to have less attenuation than 1, 3 butylene glycol. In conclusion, it was known in the art as taught by Boun that mediums with human tissue acoustic properties were needed for ultrasonic imaging. Further it was known that 1, 2 butylene glycol had both the acoustic impedance properties and the velocity matching human tissue as taught by Hawrylak'76. The relationship between attenuation and viscosity was understood as taught by Shafer and that 1, 2 butylene glycol was less viscous than 1, 3 butylene glycol as taught by Hawrylak'27. One of ordinary skill would then expect 1, 2 butylene glycol to have less attenuation while matching acoustic properties to human tissues. It would have been within the understanding of one with ordinary skill in the art to be motivated to try 1,2 butylene glycol over 1, 3 butylene glycol.

Citations:

Hawrylak, Brent et al. Ultrasonic Velocity and Volumetric Properties of Isomeric

Butanediols Plus Water Systems. Can. J. Chem, 1998: 76 (464-468) [referred herein as Hawrylak'76].

Hawrylak, Brent et al. Viscosity, Surface Tension, and Refractive Index Measurements

of Mixtures of Isomeric Butanediols with Water. Journal of Solution Chemistry, 1998: Vol 27, No 9 (827-841) [referred herein as Hawrylak'27]

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947.

The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768